PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 97 202 a/se	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/02708	International filing date *(day/month/year)* 14.03.2003	Priority date *(day/month/year)* 14.03.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant ANGIOMED GMBH & CO. MEDIZINTECHNIK KG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.10.2003	02.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Skorovs, P Telephone No. +49 89 2399-6973

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/02708

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-24 as originally filed

Claims, Numbers

1-24 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 20-24

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 20-24

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-19 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-7,11,18
	No:	Claims	1, 8-10, 12-17, 19
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations

see separate sheet

Reference is made to the following documents:

D1: WO 01 01888 A
D2: US-A-5 741 327
D3: WO 9943378 A

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. No international search report has been established for method claim 24, since this claim relates to a diagnostic method practised on the human body defined by a step of "visualising a lumen supported by a tubular metal structure". The International Preliminary Examining Authority is not required to carry out an international preliminary examination on such claims (Rule 66.1 (e) PCT).

2. No international search report has been established for claims 20-23, since the requirement of unity of invention is not complied and the applicant has not paid a second search fee.
The International Preliminary Examining Authority is not required to carry out an international preliminary examination on such claims (Rule 66.1 (e) PCT).

Re Item IV
Lack of unity of invention

Claims 1-19 are directed to a tubular radially expandable metal structure comprising a plurality of expansible rings arranged adjacent one another, and adjacent rings being linked by bridges, whereby said bridges exhibits reduced electrical conductivity,
whereas claims 20-23 are directed to a method of manufacturing a tubular radially expandable metal structure comprising a plurality of expansible rings arranged adjacent one another, and adjacent rings being linked by bridges, whereby said bridges exhibit reduced electrical conductivity.

The common matter between both of the above groups of the claims is not novel over the disclosure of document D1, for example document D1 discloses (see page 3, line 2 - page 5, line 9; fig. 5,6) a tubular radially expandable metal structure comprising a plurality of

expansible rings arranged adjacent one another, and adjacent rings being linked by bridges, whereby said bridges exhibit reduced electrical conductivity.

Therefore, according Rules 13.1 and 13.2 PCT the requirement of unity is not fulfilled, because there are no common special technical features.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Document D1 discloses (see page 3, line 2 - page 5, line 9; fig. 5,6) a tubular radially expandable metal structure comprising a plurality of expandable rings (16) arranged adjacent one another, and adjacent rings being (16) linked by bridges (20), whereby said bridges (20) exhibit reduced electrical conductivity.
The features of independent claim 1 are therefore anticipated by document D1 (see passages cited above).
Hence, the subject-matter of claim 1 does not meet the requirement of novelty (Art. 33(2) PCT).

2. Moreover, the additional features of claims 12-17 and 19 are also disclosed in document D1 (see page 3, line 2 - page 5, line 9; fig. 1,5,6).
Hence, the subject-matter of the above claims does not meet the requirement of novelty (Art. 33(2) PCT).

3. It is well known that, when the stent is formed from a material such as nickel titanium alloy, an oxide layer always forms on the surface of the nickel titanium stent (see D2 column 7, lines 59-61).
Hence, the subject-matter of claims 8-10 does not meet the requirement of novelty (Art. 33(2) PCT).

4. The additional features of claims 2-7 are common practice in this technical field (see D2, column 7, line 37 - column 11, line 13; fig. 7-19). This also applies to the claim 11 (see D3, page 6, lines 6-9; fig. 2D), and claim 18 (see D2, column 1, lines 42-43). It would be therefore have been obvious to the person skilled in the art, to apply these features to a delivery system according to document D1.
Hence, subject-matter of the above claims does not involve an inventive step (Art. 33(3)

PCT).

5. Claim 1 should have been worded in the two-part form incorporating in its pre-characterising portion the features disclosed in the closest prior art (D1) (Rule 6.3 (b) PCT).

6. The closest prior art (D1) should have been indicated in the description (Rule 5.1 (a) (ii) PCT).